

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Moviprep, powder for oral solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

The ingredients of Moviprep are contained in two separate sachets.

Sachet A contains the following active substances:

Macrogol 3350	100 g
Sodium sulfate anhydrous	7.500 g
Sodium chloride	2.691 g
Potassium chloride	1.015 g

Sachet B contains the following active substances:

Ascorbic acid	4.700 g
Sodium ascorbate	5.900 g

The concentration of electrolyte ions when both sachets are made up to one litre of solution is as follows:

Sodium	181.6 mmol/L (of which not more than 56.2 mmol is absorbable)
Sulfate	52.8 mmol/L
Chloride	59.8 mmol/L
Potassium	14.2 mmol/L
Ascorbate	29.8 mmol/L

Excipient(s) with known effect:

This product contains 0.233 g of aspartame per sachet A.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Powder for oral solution.

Product imported from Italy

Free flowing white to yellow powder in Sachet A.

Free flowing white to light brown powder in Sachet B.

4 CLINICAL PARTICULARS

As per PA1336/001/001

5 PHARMACOLOGICAL PROPERTIES

As per PA1336/001/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Aspartame (E951)

Acesulfame Potassium (E950)

Lemon flavour containing maltodextrin, citral, lemon oil, lime oil, xanthan gum, vitamin E

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf-life expiry date of this product is the date shown on the container and outer package of the product on the market in the country of origin.

Reconstituted solution 24 hours

6.4 Special precautions for storage

Sachets: Store below 25°C.

Reconstituted Solution: Store below 25°C. The solution may be refrigerated. Keep the solution covered.

6.5 Nature and contents of container

A paper / low density polyethylene / aluminium / low density polyethylene sachet containing 112 g of powder ('sachet A') and a paper / low density polyethylene / aluminium / low density polyethylene sachet containing 11 g of powder ('sachet B'). Both sachets are contained in a transparent bag. One pack of MOVIPREP contains a single treatment of two bags.

Pack sizes of 1 pack of a single treatment.

6.6 Special precautions for disposal and other handling

Reconstitution of Moviprep in water may take up to 5 minutes and is best performed by adding the powder to the mixing vessel first followed by the water. The patient should wait until all the powder has dissolved before drinking the solution.

After reconstitution in water Moviprep consumption may begin immediately or if preferred it may be cooled before use.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

Primecrown 2010 Limited
4/5 Northolt Trading Estate
Belvue Road
Northolt
Middlesex UB5 5QS
United Kingdom

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1633/070/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 18th May 2018

10 DATE OF REVISION OF THE TEXT